REMARKS

Claims 1-13 are pending. Claims 8-13 have been withdrawn. Claim 7 has been cancelled without prejudice or disclaimer of subject matter. Claim 1 has been amended to further define Applicants' invention by including the limitations of cancelled Claim 7. Claim 1 is in independent form. Favorable reconsideration and allowance of the subject application are respectfully requested in view of the following comments.

Claims 1-7 stand rejected under 35 U.S.C. § 103(a) as allegedly being obvious over U.S. Patent No. 4,486,436 (Sunshine et al.) and U.S. Patent No. 4,943,565 (US '565 Tencza et al.). Claims 1-7 stand rejected under 35 U.S.C. § 103(a) as allegedly being obvious over Canadian Patent No. 1,336,687 (CA '687 Tencza et al.). Applicants respectfully traverse these rejections, in view of the comments set forth below.

Among the noteworthy features of amended Claim 1 is a solid pharmaceutical dosage form comprising caffeine, wherein at least 95 % of the caffeine dissolves within 5 minutes, when measured by USP, Type II Apparatus (Paddles) set at 50 rpm.

Sunshine et al. is directed to analgesic and anti-inflammatory compositions comprising caffeine together with a selected non-narcotic analgesic/nonsteroidal anti-inflammatory drug and/or a selected narcotic analgesic.

Applicants' have reviewed Sunshine et al. and have not found it to disclose a composition comprising caffeine, wherein at least 95 % of the caffeine dissolves within 5 minutes, when measured by USP, Type II Apparatus (Paddles) set at 50 rpm, as set forth in Claim 1. Accordingly, Claim 1 is patentable over Sunshine et al.

US '565 Tencza et al. relates to an analogesic tablet containing aspirin, acetaminophen, caffeine, and a low-substituted hydroxypropylcellulose that exhibits an

improved dissolution rate. In US '565 Tencza et al., dissolution rates for aspirin (ASA), acetaminophen (APAP), and caffeine (CAFF) are provided in Tables IV and V. In Table IV, sample CW-3446-54B exhibits the best results where 80% of the caffeine is dissolved in 5 minutes. In Table V, sample CW 3446-58 exhibits 75% dissolution of caffeine in 4 minutes. Notably, the data presented in Tables IV and V demonstrate that the compositions of US '565 Tencza et al. do not meet the requirement set forth in Claim 1, where at least 95 % of the caffeine dissolves within 5 minutes, when measured by USP, Type II Apparatus (Paddles) set at 50 rpm. As such, Claim 1 is patentable over US '565 Tencza et al.

Applicants respectfully submit that US '565 Tencza et al. does not remedy the deficiencies of Sunshine et al. Neither Sunshine et al. nor US '565 Tencza et al. disclose or teach a solid pharmaceutical dosage form comprising caffeine, wherein at least 95 % of the caffeine dissolves within 5 minutes, when measured by USP, Type II Apparatus (Paddles) set at 50 rpm, as set forth in Claim 1. Therefore, Claim 1 is patentable over Sunshine et al. and US '565 Tencza et al. whether considered separately or in combination.

CA '687 Tencza et al. was discussed previously in Applicants' responses filed August 13, 2007 and February 4, 2008. Table I of CA '687 Tencza et al., shows the dissolution rate of caffeine in samples CW-3708-29B and CW 3708-30. For CW-3708-29B, 85% of the caffeine is dissolved after 5.7 minutes (+/- 0.9). For CW 3708-30, 85% of the caffeine is dissolved after 39 minutes (+/- 6). Here again, the compositions disclosed do not meet the requirement set forth in Claim 1, where at least 95 % of the caffeine dissolves within 5 minutes, when measured by USP, Type II Apparatus (Paddles) set at 50 rpm. As such, Claim 1 is patentable over CA '687 Tencza et al.

The Office Action contends that "[i]t would have been obvious that at least 95% of the caffeine in the caffeine composition tablet of TENCZA et al. would dissolved within 5 minutes since the reference teaches that at least 75% of the caffeine-acetaminophen tablet dissolves in under 45 minutes." (See page 8 of the Office Action dated April 30, 2008).

Applicants respectfully disagree. Tencza et al. does not state that "at least 75% of the caffeine-acetaminophen tablet dissolves in under 45 minutes." Rather, Tencza et al. states that "at least 75% of the tablet dissolves in under 45 minutes." (See, for example, CA '687 Tencza et al., p. 21, lines 11-13). Moreover, the statement is directed to all the components in the tablet, and NOT just the caffeine portion as set forth in Claim 1. Thus, CA '687 Tencza et al. does not disclose that at least 95 % of the caffeine dissolves within 5 minutes, as required by Claim 1. In fact, the data provided by Tencza et al. in CA '687 Tencza et al. demonstrates otherwise (see discussion above). As such, CA '687 Tencza et al. does not disclose a solid pharmaceutical dosage form comprising caffeine, wherein at least 95 % of the caffeine dissolves within 5 minutes, when measured by USP, Type II Apparatus (Paddles) set at 50 rpm. Accordingly, Claim 1 is patentable over CA '687 Tencza et al.

Claims 2-6 directly or indirectly depend from Claim 1. For at least the same reasons discussed above for Claim 1, Claims 2-6 are patentable over Sunshine et al., US '565 Tencza et al. and CA '687 Tencza et al., taken separately or in combination.

In view of the foregoing remarks, Applicant respectfully requests favorable reconsideration and allowance of the claims in the present application.

Applicants' undersigned attorney may be reached in our office by telephone at (732) 524-1767. All correspondence should continue to be directed to our below listed address.

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